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STATE PASS TO DHHS/NIH/FIC FOR KBIALY
WHA/BSC

E.O. 12958: N/A
TAGS: TBIO KSCA OSCI BR
SUBJECT: APPROVAL OF NIH RESEARCH PROJECT ENTITLED "LONG TERM IMPACT AND INTERVENTION FOR DIARRHEA IN BRAZIL"

REFS: A) 05 STATE 113144, B) 05 BRASILIA 1719

¶1. On January 15, 2007, Embassy received from the Brazilian Ministry of Foreign Affairs, Division of Science and Technology, (DCTEC/MFA) an official notification (number 003, dated January 15, 2007) approving the research project proposal entitled "Long Term Impact and Intervention for Diarrhea in Brazil," (contract number AI026512-16), under the direction of Dr. Aldo Angelo Moreira Lima. Informal translation of the approval notice follows:

¶2. Begin text:

"Dear Counselor,

This is to inform that after consultations with the appropriate federal agencies, the project titled "Long-term Impact and Intervention for Diarrhea in Brazil," to be developed by Dr. Aldo Angelo Moreira Lima, from Federal University of Ceara (UFC), and financially supported by the National Institutes of Health (NIH), was approved by the Brazilian Government, with the following provisos:

The National Commission on Research Ethics (CONEP), drawing its authority from CNS Resolution 196/96, through Opinion no. 760/2006, expresses its approval of the proposed research project with the recommendation to address the below-mentioned issues before the project starts, which should be monitored by the Research Ethics Committee (CEP) and reported to CONEP.

1) Page 39 of the project states that the oral use of arginine, alanyl-glutamine and glycine is experimental and there is no way to predict all possible present and future risks associated with this research. On this issue, the Free and Informed Consent Agreement must better explain the reimbursement for possible expenses in the research, as well as the coverage for possible damages caused to research individuals and it must be made clear who will be responsible for covering against these damages and where the volunteer will find help in an emergency. The responsibility of the researcher for any damage shall also be clarified. The mere mentioning of the right to legal claim is not enough.

2) We are waiting for the approval document issued by the Research Ethics Committee of the University of Virginia (United States) in accordance with item VII.1 of Resolution 292/99. We point out that page 45 of the project states that the protocol and the Consent Agreement and any subsequent change will be revised and approved by both ethics committees (a local one at UFC and another at the University of Virginia).

3) Page 45 of the protocol should clarify the references to resolutions and/or a statement should be attached saying that in the case of needing to interrupt the study, this will follow the provisions under items III.3 "z" ("cease the study only after assessing the reasons for discontinuity by the CEP which approved it") and VII.13 "f" ("The research ceased without explanation

accepted by the CEP which approved it is considered unethical") of CNS Resolution 196/96 and item III.2"e" of CNS Resolution 251/97 (explanation submitted to CEP). We point out that the interruption of the study should be bound to a bilateral decision between NIAID and UFC and acceptable only for reasons of protecting its volunteers.

4) Inclusion and exclusion criteria are defined. In the inclusion criteria, however, there is no reference to 2,000 family members who are to be the donors of genetic material.

5) As to the Free and Informed Consent Agreement (Termo de Consentimento Livre e Esclarecido - TCLE), two TCLEs have been presented (one for the research with micronutrients and another for genetic research), as part of the participants will perform only the procedures relative to the (family) genetic evaluations and others will perform both genetic procedures and the clinic part of the research with micronutrients. These two TCLEs, however, released on April 8, 2005, predate the version initially presented (November 23, 2005) and precede the date of CONEP Opinion 352/2006 (dated April 20, 2006). It is understood that the TCLE versions must be dated later than the CONEP Opinion date.

6) In the TCLE specific for micronutrients research, the sentence which considers free medical assistance and free supplies in test as benefits must be excluded. This fact might be considered an infringement of autonomy, as it may be considered a possible inducement to the subject of the research and infringe its autonomy, as it does not really constitute a benefit to the subjects, because access to treatment should be guaranteed to all. This sentence might be placed for example under an item titled "costs".

7) In the TCLE specific for genetic research, no reference to prescribing the medicine under study should be included, which is mentioned in some items."

¶3. The Embassy sees no adverse foreign policy implications with respect to this research project. We reiterate the importance of complying with Brazilian law on the export of data and biological material and medical research involving human beings.

SOBEL